

PATENT
Attorney Docket No.: 50623-00041

REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 1, 2, 5, 9-13, 15-18, 20-22, and 24-44 are pending.
- Claims 1, 2, 5, 9-13, 15-18, 24-34, and 36-44 are rejected.
- Claim 35 is withdrawn from consideration.

Applicants have amended paragraph 22 and paragraph 24 of the specification to correct obvious errors. In paragraph 22, a volatile solvent was defined as a solvent with a boiling point greater than 130°C. One of ordinary skill in the art clearly recognizes that volatile solvents are solvents with generally lower boiling points. Therefore, this correction does not add new matter. Likewise, in paragraph 22, a high boiling point solvent is referred to as a volatile solvent. One of ordinary skill in the art clearly recognizes that high boiling point solvents tend to be non-volatile solvents. Therefore, this correction also does not add new matter.

Applicants have amended Claim 1 to recite that the "applying" step comprises "spraying" and to make the language describing the heating temperature commensurate with the language in the specification.

Applicants have amended Claims 2, 17, 18, 20, 22, 27, 29, 33, 37, 39, 41, 43, and 44 to make the language describing the medical device commensurate with similar language in the specification.

Applicants have amended Claim 5 to include the limitations of Claim 8 and Claim 14.

Applicants have amended Claim 9 to change its dependency because of the cancellation of Claim 8. This amendment does not change the scope of Claim 9.

Applicants have amended Claim 21 to reflect the changes made to Claim 5.

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Applicants have amended Claim 24 to reflect the changes made to Claim 1. This amendment does not change the scope of Claim 24.

Applicants have amended Claim 26 as the Examiner suggested.

Applicants have amended Claim 31 to reflect the changes made to Claim 1.

Applicants have amended Claims 42-44 to recite that the "applying" step comprises "spraying" and to make the language describing the heating temperature commensurate with the language in the specification.

Additionally, some of the above claims have been amended to fix grammatical problems, as shown.

Paragraph 9

Applicants have amended the specification as indicated above. Support for this information can be found in claim 21, as filed. Therefore this amendment does not amount to new matter.

35 USC § 112

Paragraph 11

The Examiner has rejected claims 1-2, 5, 8-16, 21-22, 24-26, 28, 30-32, 34, 36, and 41-44 under 35 USC § 112 for failing to comply with the written description requirement. Specifically, the Examiner objects to the phrase "medical device". Applicants have modified this phrase to "implantable medical device". Thus, this phrase now matches the specification, and Applicants believe that they have rectified this rejection.

Similarly, the Examiner contends that "application temperature" or "maintenance of the 'temperature greater than ambient temperature'" amounts to new matter in claims 1-2, 21, 24-25, 31, 36, and 41-44. Applicants have amended Claims 1 and 41-44, as shown above. Specifically, the language now parallels that of Claim 21, as filed.

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Step a) of claim 1 after amendment reads: "heating the medical device to a temperature greater than ambient temperature". Support for this step can be found in paragraph 24 of the application as filed. Support for this heating occurring before the applying step is also found in this paragraph. "Preheating of the stent prior to applying a composition containing actinomycin D . . ." yields an example of a heating step before a coating step. Paragraph 24 discloses a temperature to which the stent can be heated. This temperature is a temperature above ambient temperature.

In any case, adding claim limitations that were disclosed in the application as filed does not amount to new matter. Therefore, please remove these 35 USC § 112 rejections.

In claim 26, Applicants have amended "41" to read "39", as the Examiner suggested.

Paragraph 12

Applicants note that the MPEP has not been subjected to or adopted using the rulemaking procedures of the Administrative Procedure Act. Therefore, while binding on the patent office, the MPEP is not binding on the public or on Applicants. Applicants have reviewed the rules in the Code of Federal Regulations, Title 37, and find no requirement to cite page or line numbers for newly added limitations in claims. If Applicants have overlooked the appropriate rule, please point it out. Nonetheless, when Applicants believe it is useful or when it expedites issuance of the application, Applicants will strive to do as the Examiner requests.

Claim interpretations

Paragraph 13

Applicants have amended claims 17-18, 20-21, 27, 29, and 33 to recite "implantable medical device", when appropriate, and "stent", when appropriate.

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Paragraph 15

Claims 1 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Pursley (US 6,030,371).

Pursley teaches making a medical device. Pursley does not teach applying a coating substance onto a medical device. Pursley teaches applying a coating substance onto a mandrel. The mandrel is not a medical device. Pursley teaches applying a coating substance onto a filament. The filament is not a medical device. And Pursley teaches applying a coating substance onto a catheter liner. While a catheter may be a medical device, a catheter liner is not.

The Examiner stretches English in equating a liner with a medical device. At best, Pursley's liner is a component of a medical device.

Nonetheless, even if the liner is a medical device it certainly is not an "implantable medical device", as Claims 1 and 41 require.

Since Pursley does not teach each and every element of Claims 1 and 41, it does not anticipate Claims 1 and 41. This reason alone requires removing this rejection; please do so.

Moreover, Pursley does not teach spraying a fluid-containing coating substance onto a heated medical device. Pursley teaches a variety of powder coating techniques, which explicitly use heated substrates. Every time Pursley mentions using heat to consolidate the polymer material, Pursley describes the polymer material as a powder or as molten (not dissolved). When Pursley mentions heated substrates, Pursley links those substrates in every case with powdered or molten polymer material. While Pursley does say that the polymer material can be solvated, Pursley fails to describe any embodiments in which this is so. Not once does Pursley link a solvated polymer material with a heated substrate. The only reason the Examiner does this is that the Examiner has used Applicants' disclosure as a road map. Using hindsight, it is easy to take Applicants' disclosure and search and find Pursley. But one of ordinary skill in the

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art would never take Pursley's disclosure and create Applicants' invention. To get from Pursley's teachings to Applicants' invention requires invention on the part of a skilled artisan. Pursley does not anticipate Applicants' invention.

This reason by itself is sufficient to remove Pursley as an anticipatory reference. Please do so. Otherwise, please remove Pursley because it does not teach coating an implantable medical device, as discussed above.

Paragraph 16

Claims 1, 2, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Bouchier et al. (US 6534,112 B1).

As amended, these claims require application to be by spraying. Bouchier does not teach spraying. Therefore, Bouchier does not teach each and every element of these claims and does anticipate Claims 1, 2, or 36. Please remove this rejection.

Paragraph 18

Claims 2, 24, 36, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg (US 5,464,650) in view of Pursley (US 6,030,371).

Berg teaches an "extremely simple method" for coating a polymer and a drug onto a stent. (Berg, Col. 2, line 42.) Berg demands a drug. Berg also teaches that "the overall coating should be thin enough so that it will not significantly increase the profile of the stent. (Berg, Col. 2, line 47.) Berg's method can coat both the inner and outer surfaces of the stent. (Berg, Col. 3, line 51). Berg also wants a uniform coating. (Col. 4, line 29).

Pursley teaches that, when a liner is used in Pursley's method, typically the resulting medical device receives a polymer coating five times as thick as the underlying medical device. (Col. 5, line 35.) Pursley does not teach that heat application is suitable for a drug.

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Procedure requires the patent office (Examiner) to set out a *prima facie* case of obviousness. This *prima facie* case consists of several elements including a motivation on the part of a skilled artisan to combine the references and a reasonable expectation of success on the part of a skilled artisan.

When Applicants filed the current application, an artisan looking at Berg could not reasonably expect success in supplying the heating step taught by Pursley. First, the skilled artisan would not expect to maintain the simplicity of Berg by adding a heated mandrel to the process. Moreover, the skilled artisan would also have to abandon hope of coating the inside of the medical device, if he or she adopted the heated mandrel taught by Pursley.

But most importantly, the skilled artisan could not have reasonably expected to achieve the increased solvent removal speed, without inadvertently degrading the more fragile drug. There is no evidence of record that shows that a skilled artisan would have concluded that it would be worthwhile to heat Berg's stents. While solvent removal speed would potentially be improved, without experimentation an ordinary skilled artisan would not have known whether or not the drug would degrade too much. And if the skilled artisan was not interested in a drug-containing coating, the artisan would not have selected Berg as a starting point.

Since a skilled artisan at the time the current invention was made could not reasonably have expected a successful marriage of Berg with the heating step of Pursley, that combination does not make Applicants' invention obvious. Please remove this rejection.

Paragraph 19

Claims 5, 8-14, 22, 26-27, 29, 33, 34, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al. (US 5,558,900).

The current claims distinguish over Fan because Fan does not teach spraying and these claims require spraying. The Examiner contends that a skilled artisan would see

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immersion, which Fan teaches, as equivalent to spraying, which is required by these claims.

Prima facie obviousness requires a reasonable expectation of success. For the rejection outlined here to be valid, a skilled artisan would have to reasonably expect that spraying and immersion are, in fact, equivalent. There is no basis for presuming that knowledge in a skilled artisan. Record evidence shows instances of the equivalence of spraying and immersion and instances that spraying and immersion, in fact, lead to different results. For instance, Berg Examples 3 and Example 4 show that immersing a medical device in a polymer-solvent combination yields coatings that undesirably become detached, while Example 5 shows that spraying the polymer-solvent combination onto the device yields a well-attached coating. Therefore, a skilled artisan had conflicting evidence of the equivalence of immersion and spraying on the invention date. This conflict precludes a REASONABLE conclusion that these application methods are equivalent.

Because a skilled artisan would lack a reasonable expectation of success in making the substitution identified in this rejection, the Examiner has not made out obviousness or obviousness has been overcome. Please remove this rejection.

Paragraph 20

Claims 8-10, 15-18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Zhong (US 6,156,373).

Fan fails to teach spraying. Zhong may teach the equivalence of spraying and immersion, but in view of Berg, as discussed above, a skilled artisan could not reasonably conclude that spraying and immersion were equivalent in the instant systems without experimentation. In fact, some of Zhong's disclosed polymers are the same ones used in Berg's examples. Therefore, a skilled artisan had conflicting evidence of the equivalence of immersion and spraying on the invention date. This conflict precludes a REASONABLE conclusion that these application methods are equivalent.

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Because a skilled artisan would lack a reasonable expectation of success in making the substitution identified in this rejection, the Examiner has not made out obviousness or obviousness has been overcome. Please remove this rejection.

Paragraph 21

Claim 21, 30, 31, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Pursley.

Claims 21, 30, 31, 43, and 44 depend from Claim 5, above, and therefore, have all the limitations of Claim 5. Thus, these claims are patentable based on the limitations that make Claim 5 patentable. The Examiner has not made out *prima facie* obviousness because she has not explained how this combination makes Claim 5 obvious. The current rejection is moot. But Applicants do not acquiesce to the Examiner's position in this rejection and reserve the right to deal with the specifics of the rejection in the future, if that becomes necessary.

Paragraph 22

Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fan in view of Whitbourne.

Claims 28 and 32 depend from Claim 5, above, and therefore, have all the limitations of Claim 5. Thus, these claims are patentable based on the limitations that make Claim 5 patentable. The Examiner has not made out *prima facie* obviousness because she has not explained how this combination makes Claim 5 obvious. The current rejection is moot. But Applicants do not acquiesce to the Examiner's position in this rejection and reserve the right to deal with the specifics of the rejection in the future, if that becomes necessary.

Paragraph 23

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pursley in view of Whitbourne.

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Claim 25 depends from Claim 1, above, and therefore, has all the limitations of Claim 1. Thus, these claims are patentable based on the limitations that make Claim 1 patentable. The Examiner has not made out *prima facie* obviousness because she has not explained how this combination makes Claim 1 obvious. The current rejection is moot. But Applicants do not acquiesce to the Examiner's position in this rejection and reserve the right to deal with the specifics of the rejection in the future, if that becomes necessary.

Paragraph 24

Claims 5, 11-14, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofstead (US 4,977,901).

As a whole Ofstead teaches that slowly removing solvent and then heat curing the resulting polymer results in a uniform coating. To get from Ofstead to Applicants' invention, one of ordinary skill in the art would have to reject slowly removing the solvent. "Air drying of the coating before heat treatment **for a period of time greater than 3 hours is preferred.**" (Ofstead, Col. 5, line 28). Ofstead teaches that the duration of the air drying has a preferred range, not that air drying is unnecessary. In fact, Ofstead says in the next sentence that without air-drying an inferior coating forms.

The Examiner cites case law to support that it is obvious to skip a step if the step is unwanted or unneeded. But one of ordinary skill in the art is not apt to sacrifice coating quality without a concomitant benefit. Without some other, yet unidentified, benefit, one of ordinary skill would not be motivated to sacrifice coating quality. Also, following this reasoning, one of ordinary skill in the art would have expected inferior coatings to result from omitting the air-drying step. If that is the case, Applicants' production of acceptable coatings is unexpected.

Moreover, to get from Ofstead to Applicants' invention, one of ordinary skill in the art would have had to reject Ofstead's teachings regarding heat treatment time. Ofstead discloses a typical treatment of at minimum 15 minutes or nine hundred seconds. While not necessarily limiting the heat treatment time, Ofstead teaches one of ordinary skill a ballpark figure around which he or she would have optimized. But Applicants'

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heating time is nine times shorter than Ofstead. To get from Ofstead's communicated times to those of Applicants would, once again, require one of ordinary skill in the art to reject Ofstead's reasonable teachings related to time. Ofstead does not suggest that a shorter time is reasonable. In fact, because Ofstead does not intentionally use its heat treatment to remove solvent, but rather to anneal the coating, Ofstead inherently requires longer rather than shorter heating times.

One of ordinary skill in the art sees Ofstead as follows. First, a polymer coating is applied to a medical device. Next, air-drying removes most of the solvent to avoid bubbles in the coating caused by rapid solvent vaporization upon exposing the coating to heat. Finally, the coating is heat treated long enough to anneal the polymer coating.

One of ordinary skill would not start with Ofstead if he or she were aiming at Applicants' process. At the heart of Applicants' process is using heat to rapidly drive off solvent by vaporizing it—the very thing Ofstead avoids.

Since one of ordinary skill in the art would not be motivated to make the changes necessary to Ofstead's process. Ofstead does not make these claims obvious. Please remove this rejection.

Paragraph 25

Claims 5, 8-14, 17-18, 20, 26-27, 29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (US 5,980,972) in view of Roz (3,882,816) or Finlay (4,865,879).

Ding teaches the advantages of applying the active agent and the polymer from separate solutions. Applicants' claim combines the active agent and the polymer. Claim 5 requires that the composition contain a fluid, an active agent, and a polymer. Therefore, neither Ding nor these Ding combinations suggest or make obvious Applicants' invention.

Please remove this rejection.

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Paragraph 26

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112).

Claim 24 depends from Claim 1, above, and therefore, has all the limitations of Claim 1. Thus, these claims are patentable based on the limitations that make Claim 1 patentable. The Examiner has not made out prima facie obviousness because she has not explained how this combination makes Claim 1 obvious. The current rejection is moot. But Applicants do not acquiesce to the Examiner's position in this rejection and reserve the right to deal with the specifics of the rejection in the future, if that becomes necessary.

Please remove this rejection.

Paragraph 27

Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Zhong.

As amended, these claims require application to be by spraying. Bouchier fails to teach spraying. Zhong may teach the equivalence of spraying and immersion, but in view of Berg, as discussed above, a skilled artisan could not reasonably conclude that spraying and immersion were equivalent in the instant systems without experimentation. In fact, some of Zhong's disclosed polymers are the same ones used in Berg's examples. Therefore, a skilled artisan had conflicting evidence of the equivalence of immersion and spraying on the invention date. This conflict precludes a REASONABLE conclusion that these application methods are equivalent.

Because a skilled artisan would lack a reasonable expectation of success in making the substitution identified in this rejection, obviousness has not been made out or has been overcome. Please remove this rejection.

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Paragraph 28

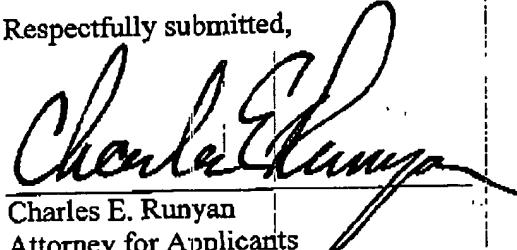
Claims 5, 14, 17, 18, 20, 21, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouchier et al. (US 6,534,112) in view of Ding or Fan.

As amended, these claims require application to be by spraying. Bouchier fails to teach spraying. In view of Berg, as discussed above, a skilled artisan could not reasonably conclude that spraying and immersion were equivalent without experimentation. Therefore, a skilled artisan had conflicting evidence of the equivalence of immersion and spraying on the invention date. This conflict precludes a REASONABLE conclusion that these application methods are equivalent.

Because a skilled artisan would lack a reasonable expectation of success in making the substitution identified in this rejection, obviousness has not been made out or has been overcome. Please remove this rejection.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



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